Avery J. Evans, MD
Mary E. Jensen, MD
Kevin E. Kip, PhD[2]
Andrew J. DeNardo, MD
Gregory J. Lawler, MD[3]
Geoffrey A. Negin, MD
Kent B. Remley, MD[4]
Selene M. Boutin, MSN, ARN
Steven A. Dunnagan, MD[5]

Index terms:
Osteoporosis, 321.56, 331.56
Spine, fractures, 321.411, 331.411
Spine, vertebroplasty, 321.1269, 331.1269

Published online before print
10.1148/radiol.2262010906
Radiology 2003; 226:366–372

Abbreviations:
ADL = activities of daily living
PMMA = polymethylmethacrylate

[1] From Radiology Associates of Tampa, 511 W Bay St, Suite 301, Tampa, FL 33606 (A.J.E., S.M.B.); Department of Radiology, University of Virginia, Charlottesville (M.E.J.); Department of Mental Health Law and Policy, University of South Florida, Tampa (K.E.K.); Department of Radiology, Methodist Hospital, Indianapolis, Ind (A.J.D.); Regional Medical Center at Hopkins County, Madisonville, Ky (G.J.L.); Lee Memorial Hospital, Fort Myers, Fla (G.A.N.); Quantum Radiology, Atlanta, Ga (K.B.R.); and Shannon West Texas Medical Center, San Angelo (S.A.D.). Received May 10, 2001; revision requested June 25; final revision received May 21, 2002; accepted June 24. **Address correspondence to** A.J.E. (e-mail: *aevans1@tampabay.rr.com*).

Current addresses:
[2] Department of Epidemiology, Graduate School of Public Health, University of Pittsburgh, Pa.
[3] Advanced Diagnostic Imaging, Goodlettsville, Tenn.
[4] Center for Diagnostic Imaging, Indianapolis, Ind.
[5] Radiology Associates, Little Rock, Ark.

Author contributions:
Guarantor of integrity of entire study, A.J.E.; study concepts, A.J.E.; study design, A.J.E., K.E.K.; literature research, A.J.E.; clinical studies, A.J.E.; data acquisition, all authors; data analysis/interpretation, A.J.E., M.E.J.; statistical analysis, K.E.K.; manuscript preparation, A.J.E., K.E.K.; manuscript definition of intellectual content, all authors; manuscript editing, A.J.E., K.E.K.; manuscript revision/review and final version approval, all authors.

Vertebral Compression Fractures: Pain Reduction and Improvement in Functional Mobility after Percutaneous Polymethylmethacrylate Vertebroplasty—Retrospective Report of 245 Cases[1]

PURPOSE: To describe the immediate outcome of a large cohort of patients who underwent percutaneous polymethylmethacrylate (PMMA) vertebroplasty for treatment of one or more vertebral fractures.

MATERIALS AND METHODS: This retrospective cohort study included seven university-based and private hospitals in the United States. Of 488 consecutive patients (mean age, 76 years) who underwent percutaneous PMMA vertebroplasty between 1996 and 1999, 245 were successfully interviewed retrospectively after vertebroplasty (median time, 7 months). Through telephone interview, patients completed our self-developed questionnaire designed to measure pain (10-point scale), ambulation (five-point scale), and ability to perform activities of daily living (ADL) (five-point scale) before and after vertebroplasty. Differences in reported pain, ambulation, and ability to perform ADL before and after vertebroplasty were evaluated with paired *t* tests. Differences in proportions were compared with the McNemar test. Subgroup analyses were performed to assess the consistency of differences in pre- and postprocedural pain and functional status by patient age, number of fractures, time from fracture to vertebroplasty, and time from vertebroplasty to questionnaire completion.

RESULTS: On a 10-point scale, mean pain decreased from 8.9 before vertebroplasty to 3.4 afterward ($P < .001$). Seventy-two percent of patients had substantially impaired ambulation before vertebroplasty compared with 28% afterward ($P < .001$). Ability to perform ADL was also significantly improved following vertebroplasty ($P < .001$). Twelve patients (4.9%) experienced symptomatic complications (none major or life threatening).

CONCLUSION: Treatment of vertebral fractures with percutaneous PMMA vertebroplasty appears to be safe and results in substantial immediate pain reduction and improved functional status. A randomized controlled trial appears warranted to assess the efficacy and safety of vertebroplasty.

Vertebral compression fractures associated with osteoporosis occur with increasing frequency as skeletal mass and bone strength diminish with the aging process (1). These fractures generally involve collapse and compression of the vertebral body, associated with a wedge deformity, which may lead to kyphotic angulation of the spine (2). In the United States alone, it is estimated that one-quarter of white postmenopausal women are affected

by fractures of the vertebrae (3), and among persons 65 years of age or older, vertebral fractures account for 150,000 hospital admissions in the United States annually (4). Vertebral compression fractures are usually associated with acute pain, which is frequently severe and functionally disabling, resulting in diminished quality of life and substantial medical care costs (3,5–7).

Conventional management of vertebral fractures includes primary relief of pain through therapy with narcotics, analgesics, nonsteroidal antiinflammatory agents, and immobilization. Mobilization, with or without a brace, and exercise are subsequently prescribed as rehabilitation progresses. With this approach, pain from the fracture generally eases by 4 weeks to 3 months (8).

More recently, stabilization of the vertebral bodies has been attempted with injection of polymethylmethacrylate (PMMA) into the fractured vertebrae through a needle (9–12). This procedure, known as percutaneous PMMA vertebroplasty, has been reported to result in substantial and immediate pain relief (11,12), perhaps because of the mechanical stabilization of the spine, or secondary to neurotoxic effects of the PMMA (13). However, the current amount of literature on the efficacy of percutaneous PMMA vertebroplasty for the treatment of vertebral fractures is limited, and to the best of our knowledge, there are no reports of large case series.

The purpose of our study is to describe the immediate outcome of a large cohort of patients who underwent percutaneous PMMA vertebroplasty for treatment of one or more vertebral fractures.

MATERIALS AND METHODS

Patient Population

Between September 1996 and November 1999, 488 patients who had undergone percutaneous PMMA vertebroplasty were identified at seven university-based and private hospitals (Tampa, Fla; Fort Myers, Fla; Little Rock, Ark; Indianapolis, Ind; Atlanta, Ga; Charlottesville, Va; Madisonville, Ky). Beginning in March 1999, in accordance with a protocol approved by our institutional review board, an attempt was made to contact each patient by telephone to collect information on the postdischarge outcome of the percutaneous PMMA vertebroplasty procedure. Before the interview, informed consent was obtained from each patient by telephone. Of these 488 patients, 40 were identified as deceased at the time of telephone contact, 75 had an outdated (wrong) telephone number, 118 could not be reached despite repeated attempts, and 10 were unable to be interviewed for other reasons (eg, unable or unwilling to participate in a telephone interview). The remaining patients formed our study population of 245 patients.

Patient Selection

The patients with back pain associated with an osteoporotic compression fracture in whom conservative medical management had failed to provide relief had been considered for the procedure in a manner previously described (12). Selection of patients had been determined by the degree and location of pain, functional disability, use of pain medication, amount of vertebral collapse, and clinical course. Disqualifying conditions included pain caused by a herniated disk or spinal stenosis, facet joint disease, or other spine abnormality not associated with the fracture. All patients whose condition had responded to conservative therapy were not considered. Adequate response to conservative therapy included patients who demonstrated satisfactory clinical improvement with nonsurgical measures such as bed rest, orally administered pain medication, and bracing.

Percutaneous PMMA Vertebroplasty Procedure

The percutaneous PMMA vertebroplasty procedure was performed in a consistent manner at each site. The patient was placed in the prone position on an angiography table with sterile conditions. Neuroleptic analgesics in the form of fentanyl citrate (Sublimaze; Abbott Laboratories, North Chicago, Ill) and midazolam (Versed; Hoffmann-LaRoche Pharmaceuticals, Manati, PR) were administered. The treated vertebral body was localized with fluoroscopic control, and the skin overlying this area was prepared and draped. The skin over the pedicle was anesthetized with 0.25% bupivacaine hydrochloride (Abbott Laboratories), followed by a deep injection of bupivacaine to and including the periosteum.

A small skin incision was made, and a disposable 11-gauge bone biopsy trocar was positioned with its tip near the center of the pedicle and advanced until the trocar tip abutted the bone. Lateral fluoroscopy was used to advance the trocar through the pedicle into the vertebral body. Prior to injection of the PMMA, venography was performed to verify that the trocar was within the vertebral body and to exclude needle placement directly within a vertebral body vein. Injection of PMMA was performed with lateral or anteroposterior fluoroscopic guidance and was continued until *(a)* hemivertebral or holovertebral filling was achieved, *(b)* no more material could be injected into the body, or *(c)* extravasation into veins or the disk space was noted.

After the procedure, patients remained immobilized with strict bed rest for 1 hour and were subsequently discharged when they had the ability to ambulate. Each investigator evaluated symptomatic complications with radiography at the time of the procedure or with a computed tomographic (CT) scan after the procedure and recorded and reported these complications.

Data Collection

Clinical characteristics of each patient and the details of the percutaneous PMMA vertebroplasty procedure, including the number and location of treated fractures, were extracted from the medical records. Three study coordinators representing the seven clinical sites contacted participating patients and conducted a telephone interview with a 12-item questionnaire that was developed specifically for the study. Because the study was retrospectively performed, the time from the percutaneous PMMA vertebroplasty procedure to questionnaire completion varied among participants, with a median time of 7.2 months (25th percentile, 3.1 months; 75th percentile, 13.6 months).

The 12-item questionnaire included questions on the date and cause of fracture and assessments of pain, ambulation, activities of daily living (ADL), and medication usage. Pain was evaluated with a verbal version of the visual analog scale: 1 = none, 10 = worst. Ambulation was evaluated with a five-point scale: 1 = normal, no pain; 2 = normal, with pain; 3 = limited, with pain; 4 = wheelchair; and 5 = bedridden. The ability to perform ADL was measured with a five-point scale: 1 = able to do ADL without pain; 2 = able to do ADL with mild pain; 3 = able to do ADL with moderate pain; 4 = able to do ADL with severe pain; and 5 = cannot do ADL because of pain. The level of medication usage was determined as one of the following: *(a)* none, *(b)* nonsteroidal antiinflammatory drugs, *(c)* oral narcotic therapy (as-needed basis), *(d)* scheduled oral narcotic therapy,

TABLE 1
Clinical Characteristics of Patient Population (n = 245)

Clinical Characteristic	Prevalence
Age	
43–65 y	35 (14)
66–75 y	81 (33)
76–85 y	101 (42)
≥85 y	26 (11)
Mean age (y) ± SD	76 ± 9
Missing patients	2
Female patients	184 (75)
No. of fractures	
1	97 (40)
2	60 (24)
3	41 (17)
≥4	47 (19)
Mean ± SD	2.4 ± 1.7
Fracture location	
T3	1 (0.4)
T4	8 (3)
T5	9 (4)
T6	15 (6)
T7	27 (11)
T8	30 (12)
T9	24 (10)
T10	30 (12)
T11	55 (22)
T12	86 (35)
L1	103 (42)
L2	71 (29)
L3	41 (17)
L4	36 (15)
L5	18 (7)
Thoracic spine (T1 through T10)	76 (31)
Thoracolumbar junction (T11 through L2)	188 (77)
Lower lumbar spine (L3 through L5)	68 (28)
Fractures in 2 vertebral column regions	41 (17)
Fractures in all 3 vertebral column regions	10 (4)
Cause of injury	
Fall	62 (26)
Minor trauma	2 (0.8)
Other	95 (39)
No precipitating event	84 (35)
Missing patients	2
Time from fracture to vertebroplasty	
Acute (≤2 wk)	52 (25)
Subacute (>2 wk to ≤2 mo)	41 (20)
Early chronic (>2 mo to 1 y)	66 (32)
Late chronic (>1 y)	48 (23)
Missing patients	38
No. of treated fractures	
Mean ± SD	2.3 ± 1.6
Patients with untreated fracture	14 (6)

Note.—Data are numbers of patients unless otherwise stated. Numbers in parentheses are percentages.

(e) intravenous narcotic therapy, or *(f)* implanted pump.

During the telephone interview (initiated after vertebroplasty), patients were asked to recall their overall level of pain and functional status prior to percutaneous PMMA vertebroplasty, as well as their level of pain and functional status following vertebroplasty (ie, generally within 2 weeks of the procedure). For the five-point scales used to measure ambulation and the ability to perform ADL, the interviewer read all five responses to the patient after asking the question. Patients were also asked whether they would have vertebroplasty performed in the future for a new compression fracture and whether they would recommend vertebroplasty to a friend who had a compression fracture.

Twenty of the 245 patients who underwent percutaneous PMMA vertebroplasty between September and November 1999 also completed the Oswestry Low Back Pain Disability Questionnaire (14) prior to percutaneous PMMA vertebroplasty and at 1 and/or 8 weeks after vertebroplasty. The Oswestry questionnaire is a frequently used reliable and valid instrument (14) that measures 10 dimensions of low back pain and functional disability resulting from pain on a scale of 0 (least affected) to 5 (most affected). For study validation purposes, Spearman correlation coefficients were calculated between responses on the self-developed questionnaire and the Oswestry questionnaire.

Radiographic Definitions

For purposes of analysis, regions of the vertebral column were categorized as follows: thoracic spine, T1 through T10; thoracolumbar junction, T11 through L2; and lower lumbar spine, L3 through L5. The time from fracture to vertebroplasty was categorized as *(a)* acute, 0–14 days; *(b)* subacute, 15–60 days; *(c)* early chronic, 61–365 days; or *(d)* late chronic, more than 365 days.

Statistical Analysis

Descriptive statistics were calculated for each questionnaire item. Crude differences in mean pre- and postprocedural levels of pain, ambulation, and ability to perform ADL were compared with paired *t* tests. In addition, because the time from vertebroplasty to questionnaire completion varied considerably among patients, analysis of covariance was used to calculate adjusted means and *P* values, taking into account the differential time. Similarly, crude proportions of reported medication usage before and after vertebroplasty were determined, with conditional (matched) logistic regression used to derive *P* values adjusted for the differential patient time from vertebroplasty to questionnaire completion. In general, the reported positive effects of vertebroplasty in terms of pain, functional status, and medication usage were slightly greater as time from vertebroplasty to questionnaire completion increased. Finally, subgroup analyses were performed to assess the consistency of differences in pre- and postprocedural pain and functional status by patient age, number of fractures, time from fracture to percutaneous PMMA vertebroplasty, and time from vertebroplasty to questionnaire completion.

RESULTS

Clinical Characteristics

All patients met established criteria for suitability for percutaneous PMMA vertebroplasty (12), including radiographic confirmation of one or more new or progressive vertebral compression fractures, diagnosis of moderate or severe back pain and/or functional disability as determined from patient history and clinical examination, failure of conservative medical therapy, ability to tolerate lying prone for 1–2 hours, and no radiculopathy secondary to spinal stenosis, retropulsed fragments, or disk herniation.

The age range of the study population was 44–98 years (mean, 76 years ± 9); 75% were women. The mean number of vertebral fractures per patient was 2.4, with 60% of the patients having multiple fractures (Table 1). Seventy-seven percent of the patients presented with at least one fracture in the thoracolumbar junction, and 28% presented with fractures in the lower lumbar region. Roughly one-third of all fractures had no known precipitating event, whereas one-quarter of the fractures were attributed to falls. Nearly half of all procedures were performed for acute or subacute fractures (within 2 months of injury). The mean number of treated fractures was 2.3, with 94% of all patients having all vertebral compression fractures treated with percutaneous PMMA vertebroplasty.

The symptomatic complication rate from the vertebroplasty procedure was 4.9% (12 patients). Seven patients suffered a rib fracture within 24 hours of the procedure. Two patients reported temporary radicular pain after the procedure, which was completely relieved in one patient and partially relieved in the other with a nerve root injection. Three patients reported a worsening of the pain after the procedure, without any explanation being found for this worsening of

pain. CT scans in these patients showed no evidence of fracture or inappropriate PMMA placement or leakage. There were no instances of death, permanent neurologic injury, or symptomatic pulmonary embolism.

Pain, Functional Status, and Quality of Life

The mean pain score for patient-recalled prevertebroplasty pain on the 10-point pain scale was 8.9 ± 1.7. In addition, 18% of the patients reported being bedridden before percutaneous PMMA vertebroplasty, with an additional 55% being either wheelchair bound or with limited ambulation (Table 2). Nearly all patients reported either inability or difficulty in performing ADL prior to vertebroplasty because of moderate or severe pain, with 67% receiving narcotic medication.

Pain score, ambulation, and ability to perform ADL were significantly improved ($P < .001$) after percutaneous PMMA vertebroplasty (Figure, Table 2). After vertebroplasty, 49% of all patients reported a pain level of only 1 or 2 on the 10-point scale, more than 70% reported normal ambulation (with or without pain), and 63% were able to perform ADL either without pain or with only mild pain. Patients also reported substantial reductions in administration of medications, including scheduled oral narcotic therapy, as a result of undergoing percutaneous PMMA vertebroplasty. Indicative of the overall success of percutaneous PMMA vertebroplasty, the majority of all patients reported a future willingness to undergo percutaneous PMMA vertebroplasty for treatment of a new compression fracture. The substantial reported reduction in pain following vertebroplasty and the overall improved functional status and reduced reliance on administration of medications remained evident after statistical adjustment for the varying times from vertebroplasty to questionnaire completion.

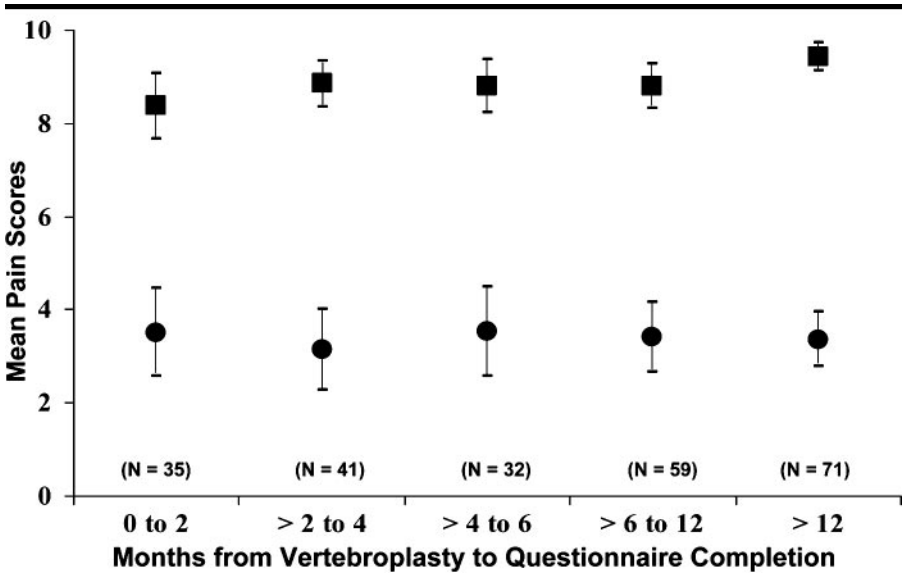
Subgroup Analyses

The substantial reduction in pain and the improvement in functional status after undergoing percutaneous PMMA vertebroplasty were consistently reported among all age groups and regardless of the number of vertebral fractures (Table 3). Similarly, the substantial benefit of percutaneous PMMA vertebroplasty was reported for both acute and chronic fractures. The accuracy of patient recall did not appear to be an appreciable source of bias because the reporting of pain and functional improvement following vertebroplasty was consistent between patients contacted within 120 days of the procedure and those with longer contact intervals (Table 3).

TABLE 2
Functional Status and Quality of Life before and after Vertebroplasty (n = 245)

Functional Status/Quality of Life Indicator	No. of Patients	Before Vertebroplasty*	After Vertebroplasty†
Mean pain score ± SD‡	239	8.9 ± 1.7	3.4 ± 2.7§
Ambulation	239		
Bedridden = 5		42 (18)	3 (1)
Wheelchair = 4		19 (8)	8 (3)
Limited, with pain = 3		112 (47)	56 (23)
Normal, with pain = 2		59 (25)	64 (27)
Normal, no pain = 1		7 (3)	108 (45)
Mean score ± SD		3.1 ± 1.1	1.9 ± 1.0§
ADL	201		
Cannot do because of pain = 5		75 (37)	17 (8)
Able to do with severe pain = 4		61 (30)	12 (6)
Able to do with moderate pain = 3		49 (24)	46 (23)
Able to do with mild pain = 2		11 (5)	49 (24)
Able to do without pain = 1		5 (2)	77 (38)
Mean score ± SD		3.9 ± 1.0	2.2 ± 1.3§
Medications	212		
None		36 (17)	98 (46)§
Nonsteroidal antiinflammatory drug		22 (10)	22 (10)
Oral narcotic		56 (26)	53 (25)
Scheduled oral narcotic		80 (38)	38 (18)§
Intravenous narcotic		6 (3)	0 (0)
Implanted pump		1 (0.5)	3 (1)
Opinion of vertebroplasty			
Would have vertebroplasty again to treat new compression fracture	239	NA	203 (85)
Would recommend vertebroplasty to a friend for treatment of fracture	237	NA	214 (90)

Note.—Data are numbers of patients unless otherwise stated. Numbers in parentheses are percentages. NA = not applicable.
* Condition preceding vertebroplasty (generally within 2 wk of procedure).
† Condition following vertebroplasty (generally within 2 wk of procedure).
‡ Scale of 1–10.
§ $P < .001$ compared with before vertebroplasty.



Mean pain scores before (■) and after (●) percutaneous PMMA vertebroplasty are plotted by the varying times from vertebroplasty to questionnaire completion. Error bars indicate 95% CIs for mean pain scores.

TABLE 3
Functional Status and Quality of Life before and after Vertebroplasty among Subgroups (n = 245)

Subgroup	No. of Patients	Mean Pain Score		Mean Ambulation Score		Mean ADL Score	
		Before Vertebroplasty*	After Vertebroplasty†	Before Vertebroplasty*	After Vertebroplasty†	Before Vertebroplasty*	After Vertebroplasty†
Age							
≤65 y	35	8.7	3.6	3.1	2.1	3.8	2.4
66–75 y	81	8.9	2.7	3.3	1.7	4.2	2.2
76–85 y	101	9.0	3.8	3.1	2.0	3.9	2.2
>85 y	26	9.0	3.2	3.0	1.9	3.8	2.0
No. of fractures							
1	97	8.7	3.3	3.2	1.8	4.0	2.1
2	60	9.1	3.3	3.1	1.8	3.9	2.3
3	41	9.1	3.9	3.0	1.9	3.9	2.4
≥4	47	9.0	3.2	3.2	2.1	3.9	2.3
Fractures in 2 vertebral column regions							
No	204	8.9	3.3	3.2	1.9	4.0	2.1
Yes	41	9.3	3.8	2.7	2.0	3.7	2.7
Time from fracture to vertebroplasty							
0–14 d	52	9.4	2.4	3.4	1.7	4.2	1.7
15–60 d	41	8.9	3.0	3.3	1.8	4.2	2.1
61 d to 1 y	66	8.6	3.6	3.0	1.9	3.7	2.2
>1 y	48	8.8	4.0	3.2	2.1	3.8	2.6
Time from vertebroplasty to questionnaire completion							
0–120 d	77	8.6	3.3	3.0	1.8	3.8	2.3
121 d to 1 y	94	8.8	3.5	3.1	2.0	3.9	2.3
>1 y	73	9.4	3.4	3.3	1.9	4.3	2.0

Note.—Missing cases: level of pain, 6; ambulation, 6; ADL, 44. $P < .001$ for all before and after vertebroplasty comparisons of pain, ambulation, and ability to perform ADL.
* Condition preceding vertebroplasty (generally within 2 weeks of procedure).
† Condition following vertebroplasty (generally within 2 weeks of procedure).

TABLE 4
Spearman Correlations between Items on Self-developed Questionnaire and Dimensions Measured with Oswestry Low Back Pain Disability Questionnaire (n = 20)*

Item from Self-developed Questionnaire	Dimension on Oswestry Low Back Pain Disability Questionnaire								
	Pain Intensity	Personal Care	Lifting	Walking	Sitting	Standing	Sleeping	Social Life	Traveling
Before vertebroplasty									
Pain	0.43	0.24	0.29	0.52	0.37	0.67	−0.06	0.44	0.41
Ambulation	−0.10	−0.13	−0.06	0.32	−0.06	0.39	−0.42	0.31	−0.19
ADL	−0.18	−0.16	−0.07	0.16	−0.04	0.37	0.21	−0.11	−0.13
After vertebroplasty†									
Pain	0.54	0.35	−0.10	0.31	0.27	0.37	0.17	0.49	0.32
Ambulation	0.70	0.66	0.23	0.59	0.60	0.52	0.03	0.69	0.56
ADL	0.42	0.26	−0.17	0.09	0.18	0.31	0.45	0.27	0.17

Note.—Oswestry questionnaire dimension of normal to restricted or absent sex life was excluded from the analysis because of substantial missing responses. Data are Spearman correlation coefficients.
* As many as two missing cases exist for some correlation pairs.
† Some patients completed Oswestry questionnaire at 1 and 8 weeks following vertebroplasty. Questionnaire that was completed closest in time to administration of self-developed questionnaire was used in analysis.

Correlations between Self-developed Questionnaire and Oswestry Questionnaire

Table 4 shows correlations between items on the self-developed questionnaire and the Oswestry Low Back Pain Disability Questionnaire. Responses about pain before percutaneous PMMA vertebroplasty, as retrospectively recalled on the self-developed questionnaire, were moderately or strongly associated with the dimensions of pain intensity, walking, standing, social life, and traveling on the Oswestry questionnaire. Reporting of pain after percutaneous PMMA vertebroplasty was similarly associated with the dimensions of pain intensity and social life. The self-developed measure of ambulation demonstrated only nominal associations with dimensions on the Oswestry questionnaire before percutaneous PMMA vertebroplasty but showed strong associations with pain intensity, personal care, walking, sitting, standing, social life, and traveling after vertebroplasty. Finally, the self-developed measure of ability to perform ADL correlated poorly with the Oswestry dimensions before vertebroplasty yet correlated modestly with pain intensity and with sleeping (inversely) after vertebroplasty.

DISCUSSION

More than 24 million Americans currently have osteoporosis (15,16), and 700,000 develop osteoporotic vertebral compression fractures each year. As the population continues to age, the incidence of these fractures is likely to increase fourfold during the next 50 years (17). The recurrent pain and physical, functional, and psychosocial impairment associated with vertebral compression fractures lead to a substantially diminished quality of life compared with age-matched controls (6).

Current medical and surgical therapies do not adequately treat the pain and disability that thousands of elderly patients endure after a vertebral compression fracture. Surgery is frequently contraindicated because osteoporotic bone does not fuse well and is too soft to hold instrumentation. Medical therapy is limited to pain control and bracing and often relies on bed rest, a therapy that itself can be dangerous, especially in an elderly patient. In fact, in addition to the well-known risks of pulmonary embolism and pneumonia, elderly patients rapidly lose bone and muscle mass when bed rest is used as therapy (18–21). Vertebroplasty offers an alternative to conventional therapy. In this retrospective uncontrolled study of patients with osteoporotic spine fractures, we found a reduction in pain and an improvement in ambulation and in the ability to perform ADL that were attributable to the vertebroplasty.

In support of the validity of this study, the magnitude of the effects observed was large and considerably exceeded what would be considered clinically meaningful. Subgroup analyses suggested that accuracy of recall was not an apparent source of bias because patients reported similar reductions in pain whether the recall time was short or long. Moreover, a beneficial effect was observed in all subgroups and for both acute and chronic fractures. Taken together, these data suggest that at least in the short term, treatment of a vertebral compression fracture with vertebroplasty results in marked pain reduction and improved functional status.

This study has limitations. First and foremost, it is based on a collection of retrospective data captured through patient recall. It is possible that patients exaggerated or simply incorrectly recalled the degree of benefit they received from vertebroplasty. Without a comparison group, we were unable to quantify the relative benefit of vertebroplasty compared with that which might be expected with medical management alone. Second, a large number of patients had died or were lost to follow-up when formal data collection efforts were initiated (243 of the 488 patients). Although we have no evidence to indicate that these patients differed from those who completed our questionnaire, these patients conceivably could have been a group that benefited less from vertebroplasty than those patients who participated in the study. Third, the reliability of the questionnaire is unknown. Nonetheless, in a small subset of patients, measures of pain and ambulation correlated well or modestly well with the Oswestry questionnaire, a validated reliable instrument. Scores for ADL did not, however, correlate with the Oswestry questionnaire.

Finally, another limitation of this study is that the time from vertebroplasty to questionnaire completion varied among patients. Although the overwhelmingly positive effects reported after vertebroplasty (eg, in terms of pain, functional status, and medications) were slightly greater as time from patient vertebroplasty to questionnaire completion increased, the magnitude of effects observed was not appreciably altered after formal statistical adjustment or when stratified by time to questionnaire completion. These results suggest that recall bias alone is an unlikely explanation for the substantial pain reduction and improvement in quality of life reported by patients after vertebroplasty.

This study is, to the best of our knowledge, the largest study of patients who have undergone vertebroplasty reported in the literature to date. Previous publications are limited to case reports and case series including fewer than 50 patients (11,12,22–25). The findings of all reports to date have suggested that vertebroplasty is beneficial in providing rapid pain relief and early ambulation soon after the procedure. The mechanism of pain relief is still unknown but has been attributed either to stabilization of the vertebral body fracture (and consequently a decrease in stimulation of the periosteum) or to a direct lysis of nociceptors in the vertebral body itself.

The safety of PMMA as a material has been well established; it is nonpyrogenic and nonmutagenic and, in the quantities used for vertebroplasty, does not cause cardiopulmonary depression. However, the potential for adverse effects must be considered (26,27). The symptomatic complication rate for patients in this series was 4.9%. Previous findings in the literature suggest that for patients with osteoporosis who have undergone vertebroplasty, the rate of clinical complications is 5%–7%, mostly consisting of minor complications such as rib fractures and temporary radicular pain (as observed in this cohort) (12,22,25). Major complications such as permanent neurologic injury or serious pulmonary embolism are rare, although the true incidence of complications and the long-term outcome of patients who undergo vertebroplasty are still not well known (12,22,25,28). No long-term side effects of vertebroplasty have yet been reported, despite the use of vertebroplasty in France since 1984 and in this country since 1995. The public health importance of osteoporotic spine fractures and the current lack of prospective data on the benefits and risks of treatment support the need for a randomized controlled trial to assess the relative efficacy and safety of vertebroplasty compared with current conventional approaches.

References

1. Melton LJ III, Kan SH, Frye MA, Wahner HW, O'Fallon WM, Riggs BL. Epidemiology of vertebral fractures in women. Am J Epidemiol 1989; 129:1000–1011.
2. Melton LJ, Chao EYS. Biomechanical aspects of fractures. In: Riggs BL, Melton LJ, eds. Osteoporosis: etiology, diagnosis and management. New York, NY: Raven, 1988; 111–131.
3. Melton LJ III. Epidemiology of spinal osteoporosis. Spine 1997; 22(suppl 24):2S–11S.
4. Jacobsen SJ, Cooper C, Gottlieb MS, Goldberg J, Yahnke DP, Melton LJ III. Hospitalization with vertebral fracture among the aged: a national population-based study, 1986–1989. Epidemiology 1992; 3:515–518.
5. Cooper C, Atkinson EJ, O'Fallon WM, Melton LJ III. Incidence of clinically diagnosed vertebral fractures: a population-based study in Rochester, Minnesota, 1985-1989. J Bone Miner Res 1992; 7:221–227.
6. Lyles KW, Gold DT, Shipp KM, Pieper CF, Martinez S, Mulhausen PL. Association of osteoporotic vertebral compression fractures with impaired functional status. Am J Med 1993; 94:595–601.
7. Ross PD, Davis JW, Epstein RS, Wasnich RD. Pain and disability associated with new vertebral fractures and other spinal conditions. Am J Epidemiol 1994; 47:231–239.
8. Tamayo-Orozco J, Arzac-Palumbo P, Peon-Vidales H, Mota-Bolfeta R, Fuentes F. Vertebral fractures associated with osteoporosis: patient management. Am J Med 1997; 103:44S–50S.
9. Galibert P, Deramond H, Rosat P, Le Gars D. Note preliminaire sur le traitement des angiomes vertebraux par vertebroplastie percutanee. Neurochirurgie 1987; 33:166–168.
10. Deramond H, Galibert P, Debussche-Depriester C. Percutaneous vertebroplasty

with methyl-methacrylate: technique, method, results (abstr). Radiology 1990; 117(P):352.
11. Gangi A, Kastler BA, Dieteman JL. Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. AJNR Am J Neuroradiol 1994; 15:83–86.
12. Jensen ME, Evans AJ, Mathis JM, Kallmes DF, Cloft HJ, Dion JE. Percutaneous polymethyl methacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. AJNR Am J Neuroradiol 1997; 18: 1897–1904.
13. Bostrom MPG, Lane JM. Future directions: augmentation of osteoporotic vertebral bodies. Spine 1997; 22 (suppl 24): 38S–42S.
14. Fairbank JCT, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy 1980; 66: 271–273.
15. Riggs BL, Melton LJ III. Involutional osteoporosis. N Engl J Med 1986; 314:1676–1686.
16. Cummings SR, Kelsey JL, Nevitt MC, O'Dowd KJ. Epidemiology of osteoporosis and osteoporotic fractures. Epidemiol Rev 1985; 7:178–208.
17. Riggs BL, Melton LJ III. The worldwide problem of osteoporosis: insights afforded by epidemiology. Bone 1995; 17(suppl 5): 505S–511S.
18. Bischoff H, Stahelin HB, Vogt P, et al. Immobility as a major cause of bone remodeling in residents of a long-stay geriatric ward. Calcif Tissue Int 1999; 64:485–489.
19. Inoue M, Tanaka H, Morwake T, Oka M, Sekiguchi C, Seino Y. Altered biochemical markers of bone turnover in humans during 120 days of bed rest. Bone 2000; 26: 281–286.
20. LeBlanc A, Schneider V, Spector E, et al. Calcium absorption, endogenous excretion, and endocrine changes during and after long-term bed rest. Bone 1995; 16(suppl 4):301S–304S.
21. Stewart AF, Adler M, Byers CM, Segre GV, Broadus AE. Calcium homeostasis in immobilization: an example of resorptive hypercalciuria. N Engl J Med 1982; 306: 1136–1140.
22. Barr JD, Barr MS, Lemley TJ, McCann RM. Percutaneous vertebroplasty for pain relief and spinal stabilization. Spine 2000; 25:923–928.
23. Debussche-Depriester C, Deramond H, Fardellone P, et al. Percutaneous vertebroplasty with acrylic cement in the treatment of osteoporotic vertebral crush fracture syndrome. Neuroradiology 1991; 33(suppl):149–152.
24. Weill A, Chiras J, Simon JM, Rose M, Sola-Martinez T, Enkaoua E. Spinal metastases: indications for and results of percutaneous injection of acrylic surgical cement. Radiology 1996; 199:241–247.
25. Cotten A, Dewatre F, Cortet B, et al. Percutaneous vertebroplasty for osteolytic metastases and myeloma: effects of the percentage of lesion filling and the leakage of methyl methacrylate at clinical follow-up. Radiology 1996; 200:525–530.
26. Convery FR, Gunn DR, Hughes JD, Martin WE. The relative safety of polymethylmethacrylate: a controlled clinical study of randomly selected patients treated with Charnley and ring total hip replacements. J Bone Joint Surg Am 1975; 57:57–64.
27. Phillips H, Cole PV, Lettin AW. Cardiovascular effects of implanted acrylic bone cement. BMJ 1971; 3:460–461.
28. Padovani B, Kasriel O, Brunner P, Peretti-Viton P. Pulmonary embolism caused by acrylic cement: a rare complication of percutaneous vertebroplasty. AJNR Am J Neuroradiol 1999; 20:375–377.